EXHIBIT A

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ATTORNEYS FOR PLAINTIFF
JOHN SPEAR

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES

JOHN SPEAR,

Plaintiff,

vs.

KONINKLIJKE PHILIPS N.V.;

PHILIPS NORTH AMERICA LLC; and

PHILIPS RS NORTH AMERICA LLC,

and DOES 1- 100, inclusive,

Defendants.

CASE NO.

COMPLAINT FOR DAMAGES

1st Cause of Action – Negligence
2nd Cause of Action – Product Liability, Design Defect
3rd Cause of Action – Product Liability, Manufacturing Defect
4th Cause of Action – Product Liability, Failure to Warn
5th Cause of Action – Breach of Express Warranty
6th Cause of Action – Breach of Implied Warranty of Merchantability
7th Cause of Action – Intentional Misrepresentation
8th Cause of Action – Concealment
9th Cause of Action – Negligent Misrepresentation

JURY TRIAL DEMAND

Plaintiff JOHN SPEAR ("Plaintiff") hereby alleges on information and belief against Defendants KONINKLIJKE PHILIPS N.V. ("Royal Phillips"); PHILIPS NORTH AMERICA

LLC ("Philips NA"); and PHILIPS RS NORTH AMERICA LLC ("Philips RS"; collectively, Royal Philips, Philips NA, and Philips RS are "Philips"), and DOES 1-100, inclusive, and each of them as follows:

SUMMARY OF COMPLAINT

1. Plaintiff brings this action for injuries caused by use of Continuous Positive Airway Pressure (CPAP) devices and mechanical ventilators manufactured by Philips, which contain polyester-based polyurethane sound abatement foam ("PE-PUR Foam").

2. On April 26, 2021, Philips made a public announcement that it had determined there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices it manufactured may degrade or off-gas under certain circumstances.

3. On June 14, 2021, Philips issued a recall in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam, because Philips determined that: (a) the PE-PUR Foam was at risk for degradation into particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain chemicals during operation. Philips further disclosed in its Recall Notice that, "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment." **A true and correct copy of the: "URGENT: Medical Device Recall," is attached hereto as Exhibit "A" and incorporated by reference as though fully set forth herein.**

4. Philips has disclosed that the absence of visible particles in the devices does not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of the degraded foam reveals the presence of harmful chemicals, including Toluene Diamine ("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").

5. Prior to issuing the Recall Notice, Philips received complaints regarding the presence of black debris/particles within the air path circuit of its devices (extending from the device outlet, humidifier, tubing, and mask). Philips also received reports of headaches, upper airway irritation, cough, chest pressure, and sinus infection from users of these devices.

6. In its Recall Notice (Exhibit One), Philips disclosed that the potential risks of particulate exposure to users of these devices include irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects. The potential risks of chemical exposure due to off-gassing of PE-PUR Foam

in these devices include headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

7. Philips recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue using their devices and that patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options.

8. In or around October, 2018, Plaintiff JOHN SPEAR began using a Philips Respironics DreamStation CPAP device, which he used nightly from the date of receipt until on or about August 25, 2021.

9. While using the device, Plaintiff JOHN SPEAR experienced throat irritation and was diagnosed with severe health issues beginning on September 16, 2021 and thereafter.

10. Plaintiff JOHN SPEAR has incurred medical expenses for medical care and to replace the device. In addition, Plaintiff JOHN SPEAR experienced throat irritation during use of the Philips recalled machine. Since being notified of the recall, Plaintiff JOHN SPEAR has experienced anxiety concerning the serious health risks Plaintiff JOHN SPEAR faces from exposure to off-gassed or degraded PE-PUR Foam in the Recalled Machines, including the recalled machine used by Plaintiff JOHN SPEAR.

11. Plaintiff JOHN SPEAR seeks to recover damages based on, inter alia, Philips' breach of express warranty, breach of implied warranties, misrepresentations, omissions, and breaches of state consumer protection laws in connection with its manufacture, marketing, and sale of devices containing PE-PUR Foam.

PARTIES AND VENUE

12. Plaintiff JOHN SPEAR is and was at the time of the incident giving rise to this Complaint, residing within the greater Los Angeles area.

13. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology business, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.

14. Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips.

15. Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

16. The true names and capacities, whether individual, corporate, partnership, joint venture, franchisee or otherwise of Defendants DOES 1-100, inclusive, are unknown to Plaintiff who sues these Defendants by fictitious names.

17. Each of the Defendants named in this Complaint as a DOE is legally responsible in some manner for the events and happenings alleged in this Complaint, and legally caused injury and damage to Plaintiff as alleged in this Complaint.

18. Plaintiff is informed, believes and thereon alleges that at all times mentioned herein, certain of the Defendant DOES are the successors in interest to each of the remaining Defendants and on that basis, are liable for any act or omission of Defendants alleged in this Complaint.

19. Venue is proper in this County because the incident giving rise to this Complaint occurred in this County and the subject product was distributed, purchased, and sold in this County.

FACTUAL BACKGROUND

A. Continuous Positive Airway Pressure Therapy

20. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

21. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruptions caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental

performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

B. Bi-Level Positive Airway Pressure Therapy

22. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP devices deliver two alternating levels – inspiratory and expiratory – of pressurized air into a person's airway, rather than a single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

C. Mechanical Ventilation

23. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into a patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

EVENTS GIVING RISE TO THE COMPLAINT

24. Philips developed, marketed, and sold a variety of CPAP and Bi-Level PAP respiratory devices and mechanical ventilators under its "Sleep and Respiratory Care" segment of its business designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments. Philips' CPAP and Bi-Level PAP

respirator devices and its mechanical ventilators typically cost several hundred, if not thousands of dollars. Philips has sold millions of these devices in the United States.

A. Philips Sleep & Respiratory Care Devices Endangered Users

25. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi-Level PAP respirators and mechanical ventilators posed health risks to users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature."

26. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices." Specifically, Philips announced that it had determined that the "PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals." In total, Philips announced that "[b]etween 3 million and 4 million" devices area targeted in the recall.

27. The list of the devices recalled by Philips (the "Recalled Devices" or "Recalled Machines") include:

Philips CPAP and Bi-Level PAP Devices

Manufactured Before April 26, 2021 Subject to Recall

Device Name/Model Type

- E30 (Emergency Use Authorization) – Continuous Ventilator, Minimum Ventilatory Support, Facility Use
- DreamStation ASV; DreamStation ST, AVPAPS; SystemOne ASV 4; C Series ASV; C Series S/T and AVAPS; OmniLab Advanced Plus – Continuous Ventilator, Non-life Supporting
- SystemOne (Q Series); DreamStation; DreamStation GO; Dorma 400; Dorma 500;

REMStar SE Auto – Non-continuous Ventilator

Philips Mechanical Respirator Devices

Manufactured Before April 26, 2021 Subject to Recall

Device Name/Model Type

- Trilogy 100 Ventilator; Trilogy 200 Ventilator; Garbin Plus, Aeris, LifeVentVentilator – Continuous Ventilator
- A-Series BiPAP Hybrid A30; Philips A-Series BiPAP V30 Auto – Continuous Ventilator, Minimum Ventilatory Support, Facility Use
- Philips A-Series BiPAP A40; Philips A-Series BiPAP A30 – Continuous Ventilator, Non-life Supporting

28. According to Philips, the PE-PUR Foam used in Recalled Devices puts users at risk of suffering from: "[i]rritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic affects."

29. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."

30. Further, Philips reported that "based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment or require medical intervention to preclude permanent impairment."

31. Philips announced that it has received reports of specific complaints from users of Recalled Devices who suffered from "headache[s], upper airway irritation, cough, chest pressure and sinus infection."

B. The Health Risks Associated with Use of the Recalled Devices Renders Them Worthless

32. As a result of the health risks associated with the use of the Recalled Devices, together with Philips' concealment of these risks from the date they were first reported to Philips or discovered by Philips through April 26, 2021, the Recalled Devices have been rendered completely worthless or, at the very least, have been substantially diminished in value.

33. The information described above, including the now-known health risks of Philips CPAP devices, Bi-Level PAP devices and mechanical ventilators, the recall, and the medical warnings and advice issued by Philips, have rendered the Recalled Devices worthless to patients with sleep apnea

and respiratory conditions. Individuals not using life-supporting ventilators must immediately discontinue their use of the Recalled Devices or continue to face serious health risks as grave as organ failure or cancer. If they choose to discontinue use of the Recalled Devices they must pay for another expensive device in order to receive effective treatment for their sleep apnea and/or respiratory conditions. Individuals using life-supporting ventilators must seek an alternative treatment before discontinuing use of the Recalled Device.

34. Recognizing this, Philips issued the following advice to patients using any of the Recalled Devices:

- "For patients using BiLevel PAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."
- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."

35. As a result of the above, Plaintiff will have to undertake considerable expense replacing the Recalled Device.

C. Philips Unreasonably Delayed its Recall

36. At no time prior to its Regulatory Update on April 26, 2021, did Philips disclose to purchasers or users of the Recalled Devices that the PE-PUR Foam contained therein may off-gas or degrade upon use. Similarly, prior to the Update, Philips did not disclose any health risks associated with use of the Recalled Device.

37. Philips have not disclosed when they first discovered or received reports from users of their Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."

38. At a minimum, as a result of user reports, Philips were aware of the off-gassing and degradation of the PE-PUR Foam used in the Recall Devices at some point prior to the recall yet continued to manufacture and sell the Recalled Devices with such awareness. During this period, Philips unreasonably and unjustly profited from the manufacture and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of development of serious adverse health effects, including organ failure and cancer.

D. Plaintiff JOHN SPEAR

39. Plaintiff JOHN SPEAR purchased and used a Recalled CPAP Device, a Philips Respironics DreamStation device numbered J176451130B68.

40. The manuals accompanying Plaintiff's device did not contain any language or warnings of health risks associated with use of the device, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects. Had Philips informed Plaintiff of these risks, he would not have used the Recalled Device.

41. Without knowing of the health risks associated with use of the Recalled Device, Plaintiff used the Recalled Device regularly to treat sleep apnea until learning of the device recall, receiving an electronic "Recall alert for certain Philips Medical devices" from Medicare.gov on or about August 25, 2021.

42. As a result of the health risks associated with continued use of the Recalled Device, Plaintiff JOHN SPEAR was diagnosed with serious medical problems.

TOLLING

43. Plaintiff had no way of knowing about Philips' conduct with respect to the health risks associated with the use of the Recalled Device.

44. Plaintiff, through the exercise of reasonable care, could not have discovered the conduct by Philips alleged herein. Further, Plaintiff did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

45. Plaintiff's first notice of the conduct alleged herein came on or about August 25, 2021.

46. For these reasons, all applicable statutes of limitations have been tolled by the discovery rule with respect to claims asserted by Plaintiff.

47. By failing to provide immediate notice of the adverse health effects associated with continued use of the Recalled Device, Philips concealed its conduct and the existence of the claims asserted herein from Plaintiff.

48. Upon information and belief, Philips intended its acts to conceal the facts and claims from Plaintiff. Plaintiff was unaware of the facts alleged herein without any fault of lack of diligence on his part and could not have reasonably discovered Philips' conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiff should be tolled.

FIRST CAUSE OF ACTION – NEGLIGENCE

(Against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, AND DOES 1-100, inclusive)

49. Plaintiff incorporates by reference paragraphs 1-48 above as though fully set forth herein.

50. Defendants had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the recalled machines, including the Recalled Devices.

51. Defendants were negligent in failing to use reasonable care as described herein in designing and manufacturing the recalled machines, as well as the machine that Plaintiff JOHN SPEAR purchased and used. Defendants breached their aforementioned duty by:

a. Failing to design the Recalled Machines so as to avoid an unreasonable and increased risk of harm of cancer and other injuries in users;

b. Including in the design of the recalled machines flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer as well as other injuries;

c. Manufacturing certain Philips machines, including the Recalled Devices, with a specific lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer as well as other injuries;

d. Otherwise negligently or carelessly designing, marketing, labeling, packaging and/or selling the Recalled Devices.

52. Defendants also negligently failed to warn or instruct the Plaintiff in the following manners:

a. The recalled machine's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer as well as other injuries;

b. The recalled machine's polyurethane PE-PUR sound abatement foam propensities for degradation, fragmentation and/or chemicalization;

c. The rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;

d. The risk of chronic inflammation resulting from the use of the recalled machines;

e. The risk of chronic infections resulting from the recalled machines;

f. The risk of blood, lung, kidney, and/or rectal cancers from exposure to the foam;

g. The need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled machines;

h. The severity of complications that could arise as a result of implantation of the recalled machines.

i. As a direct and legal result of Defendant's negligence, Plaintiff has experienced serious personal injury, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment and procedures, suffered financial and economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

Wherefore, Plaintiff JOHN SPEAR prays for judgment against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; AND PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive, as set forth below.

SECOND CAUSE OF ACTION – PRODUCT LIABILITY – DESIGN DEFECT (Against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive)

53. Plaintiff incorporates by reference paragraphs 1-52 above as though fully set forth herein.

54. The recalled machine used by Plaintiff JOHN SPEAR was not reasonably safe for its intended uses and was defective as described herein with respect to its design. As previously stated, the machine's design defects include, but are not limited to:

a. The use of polyurethane PE-PUR sound abatement foam in the recalled machines and the immune reaction that results from such material, causing adverse reactions and injuries;

b. Failing to design the recalled machines so as to avoid an unreasonable and increased risk of harm of cancer and other injuries in users;

c. Including in the design of the recalled machines flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer as well as other injuries;

d. Failing to use alternatively available sound abatement materials and/or foams in the recalled machines, such as plastic, silicone, or rubber, which would not break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping.

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the recalled machines.

55. At all times, the use of the recalled machines, as well as Plaintiff JOHN SPEAR's use of the Recalled Device and its components were at all times foreseeable and foreseen by Defendants as it was used by Plaintiff JOHN SPEAR in the manner intended by Defendants.

56. The recalled machine used by Plaintiff JOHN SPEAR was defective in design in that it failed to perform as safely as a reasonable consumer would expect when used in an intended or reasonably foreseeable manner.

57. The recalled machines, including the Recalled Device used by Plaintiff JOHN SPEAR, are further defective in that the risks of danger inherent in its design outweigh the benefits, in that the gravity of danger posed by the design was great, the likelihood that such danger would cause injury was substantial, there was feasible, safer alternative designs known to Defendants at the time of manufacture, the financial costs of an improved design were minor and there were likely no adverse consequences to the product, or to the user, that would result from an alternative design.

58. Defendants, and each of them, knew that the recalled machines, including Plaintiff JOHN SPEAR's Recalled Device, and the component parts of these CPAP/BiPAP machines would be purchased and used without inspection for defects in the design of the machine or its masks/attachments.

59. The recalled machines, including Plaintiff JOHN SPEAR's Recalled Device, and the component parts of these machines were defective when they left the control of each of these Defendants.

60. As a direct and legal result of the recalled machines, including Plaintiff JOHN SPEAR's Recalled Device, and the aforementioned defects as described herein, the Plaintiff has experienced serious health issues and serious personal injury, undergone medical treatment and will likely undergo

future medical treatment and procedures, suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

61. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling the recalled machines, including Plaintiff JOHN SPEAR's Recalled Device.

62. As a direct and legal result of one or more of the above-stated negligent acts, Plaintiff has suffered and will continue to suffer serious personal injury, medical expenses, lost income, and disability and other damages.

Wherefore, Plaintiff JOHN SPEAR prays for judgment against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive, as set forth below.

THIRD CAUSE OF ACTION – PRODUCT LIABILITY – MANUFACTURING DEFECT (Against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive)

63. Plaintiff JOHN SPEAR incorporates by reference paragraphs 1-62 above as though fully set forth herein.

64. At all times, the use of the recalled machines, as well as Plaintiff JOHN SPEAR's use of the Recalled Device and its components were at all times foreseeable and foreseen by Defendants as it was used by Plaintiff JOHN SPEAR in the manner intended by Defendants.

65. The recalled machines were defective at the time of their manufacture, development, production, testing, inspection, endorsement, sale and distribution, and at the time they left the possession of the Defendants, in that, and not by way of limitation, the products differed from the Defendants' intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

66. Defendants, and each of them, knew or should have known of the defective nature of the recalled machines, including (among other things), that the PE-PUR foam used in the recalled machine's component parts were prone to flaking, chemicalization, disintegration, that it could enter the user's airways while they slept, and created an unreasonably high risk while in use, and would foreseeably result in injury or death to the public, purchasers, and/or consumers.

67. The Defendants, and each of them, knew or should have known of the defective nature of the recalled machines, and the component parts of these CPAP/BiPAP machines, including among other things, that the PE-PUR foam used in the recalled machine's component parts was prone to

flaking, chemicalization, disintegration, that it could enter the user's airways while they slept, and created an unreasonably high risk while in use, and would foreseeably result in injury or death to the public, purchasers, and/or consumers.

68. Specifically, the Defendants improperly designed the recalled machines by manufacturing certain Philips machines, including the recalled machines, with a specific lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, as well as other injuries.

69. As a direct and legal result of one or more of the above-stated negligent acts, Plaintiff has experienced serious personal injury, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment and procedures, suffered financial and economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

Wherefore, Plaintiff JOHN SPEAR prays for judgment against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive, as set forth below.

FOURTH CAUSE OF ACTION – PRODUCT LIABILITY – FAILURE TO WARN
(Against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive)

70. Plaintiff JOHN SPEAR incorporates by reference paragraphs 1-70 above as though fully set forth herein.

71. The recalled machines, including the Recalled Device used by Plaintiff JOHN SPEAR were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings including, but not limited to, the following:

a. The recalled machine's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, as well as other injuries;

b. The recalled machine's polyurethane PE-PUR sound abatement foam propensities for degradation, fragmentation and/or chemicalization;

c. The rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;

d. The risk of chronic inflammation resulting from use of the recalled machines;

e. The risk of chronic infections resulting from the recalled machines;

f. The risk of blood, lung, kidney, and/or rectal cancers from exposure to the foam;

g. The need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled machines;

h. The severity of complications that could arise as a result of implantation of the recalled machines.

72. As a direct and legal result of the recalled machines, including the machine's aforementioned defects as described herein, Plaintiff has experienced serious personal injury, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment and procedures, suffered financial and economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

73. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective device.

Wherefore, Plaintiff JOHN SPEAR prays for judgment against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive, as set forth below.

FIFTH CAUSE OF ACTION – BREACH OF EXPRESS WARRANTY (Against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive)

74. Plaintiff JOHN SPEAR incorporates by reference paragraphs 1-73 above as though fully set forth herein.

75. Philips marketed and sold the Recalled Device into the stream of commerce with the intent that the Recalled Device would be purchased by Plaintiff JOHN SPEAR and other members of the general public.

76. Philips expressly warranted, advertised, and represented to Plaintiff that the Recalled Device was safe and appropriate for human use.

77. Philips made these express warranties regarding the Recalled Device's quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the Recalled Device's packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff entered into upon purchasing the Recalled Device.

78. Philips' advertisements, warranties, representations, and omissions regarding health risks associated with the Recalled Device, were made in connection with the sale of the Recalled Device to Plaintiff. Plaintiff relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Device in deciding whether to purchase and use Philips' Recalled Device.

79. The recalled machines, including the Recalled Device used by Plaintiff JOHN SPEAR, did not conform to Philips' advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including organ failure and cancer.

80. Philips therefore breached its express warranties by placing the recalled machines, including the machine used by Plaintiff, into the stream of commerce and selling it to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Philips. These associated health effects substantially impair the use, value, and safety of the recalled machines, and rendered the machines worthless.

81. Philips was aware, or should have been aware, of the toxic or dangerous health effects from the use of the recalled machines, including the machine used by Plaintiff JOHN SPEAR, but nowhere on the package labeling or package inserts or on Philips' websites or other marketing materials did Philips warn Plaintiff that Plaintiff JOHN SPEAR was at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the recalled machines.

82. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the recalled machines, including the machine used by Plaintiff JOHN SPEAR and deceptively represented that these products were safe, healthy, and appropriate for use. Philips thus failed to ensure that the material representations they were making to consumers were true.

83. The adverse health effects associated with use of the recalled machines, including the machine used by Plaintiff JOHN SPEAR existed when they left Philips' possession or control and were sold to Plaintiff. The dangers associated with use of the recalled machines were undiscoverable by Plaintiff at the time of purchase of the Recalled Device.

84. As manufacturers, marketers, advertisers, distributors, and sellers of the Recalled Devices, Philips had exclusive knowledge and notice of the fact that the Recalled Devices did not conform to the affirmations of fact and promises.

85. In addition, or in the alternative, to the formation of an express contract, Philips made each of the above-described representations and omissions in purchasing and using the Recalled Device.

86. Philips' affirmations of fact and promises and its omissions were material, and Plaintiff reasonably relied upon such representations and omissions in purchasing and using the Recalled Device.

87. All conditions precedent to Philips's liability for its breach of express warranty have been performed by Plaintiff.

88. Affording Philips an opportunity to cure its breaches of written warranties would be unnecessary and futile here. Philips was placed on reasonable notice from user reports and its lab testing that the PE-PUR Foam in the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR was unsafe. Philips had ample opportunity either to stop using the PE-PUR Foam or to replace the PE-PUR Foam in the Recalled Devices to make them safe and healthy for use by Plaintiff but failed to do so until now.

89. As a direct and legal result of the recalled machines, including the machine's aforementioned defects as described herein, Plaintiff has experienced serious personal injury, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment and procedures, suffered financial and economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

Wherefore, Plaintiff JOHN SPEAR prays for judgment against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive, as set forth below.

SIXTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (Against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive)

90. Plaintiff JOHN SPEAR incorporates by reference paragraphs 1-89 above as though fully set forth herein.

91. Philips are merchants engaging in the sale of goods to Plaintiff and members of the general public.

92. There was a direct sale of goods from Philips to Plaintiff, creating privity between Plaintiff and Defendants.

93. At all times mentioned herein, Philips manufactured or supplied the recalled machines, including the machine used by Plaintiff JOHN SPEAR, and prior to the time of use, Philips impliedly warranted to Plaintiff that the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR was of merchantable quality, fit for their ordinary use, and conformed to the promises and affirmations of fact and omissions made on the labels and packaging, including that the machines were safe and appropriate for human use. Plaintiff relied on Philips' promises and affirmations of fact and omissions when they purchased the Recalled Device and Plaintiff JOHN SPEAR used the Recalled Device.

94. Contrary to these representations and warranties, the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR was not fit for its ordinary use and did not conform to Philips' affirmations of fact and promises and omissions because use of the Recalled Devices is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

95. Philips breached its implied warranties by selling a Recalled Device, including the machine used by Plaintiff JOHN SPEAR that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled Device was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

96. Philips was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled Devices through user reports submitted to Philips and through lab testing.

97. Privity exists because Philips impliedly warranted to Plaintiff through the warranting, packaging, advertising, marketing, and labeling that the Recalled Devices were natural, and suitable for use to treat health conditions, and made no mention of the attendant health risks associated with use of the Recalled Devices.

98. As a direct and legal result of the recalled machines, including the machine's aforementioned defects as described herein, Plaintiff has experienced serious personal injury, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment and

procedures, suffered financial and economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

Wherefore, Plaintiff JOHN SPEAR prays for judgment against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive, as set forth below.

SEVENTH CAUSE OF ACTION – INTENTIONAL MISREPRESENTATION
(Against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive)

99. Plaintiff JOHN SPEAR incorporates by reference paragraphs 1-98 above as though fully set forth herein.

100. Defendants represented to Plaintiff that the Recalled Devices were safe for human use and did not pose serious health risks to their users.

101. Defendants' representation that the Recalled Devices were safe for human use and did not pose serious health risks to their users was false.

102. Defendants made the representation that the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR, were safe for human use and did not pose serious health risks to their users knowing the representation was false in that the Recalled Devices contained PE-PUR Foam and thus were at risk of causing adverse health effects to users of the Recalled Devices which does not conform to the products' labels, packaging, advertising, and statements.

103. As a direct and legal result of the Defendants represented to Plaintiff that the Recalled Devices were safe for human use and did not pose serious health risks to their users. including the machine's aforementioned defects as described herein, Plaintiff has experienced serious personal injury, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment and procedures, suffered financial and economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

104. Defendants intended that Plaintiff rely on the representation that the Recalled Devices were safe for human use and did not pose serious health risks to their users.

105. Plaintiff reasonably relied on Defendants' representation that the Recalled Devices were safe for human use and did not pose serious health risks to their users.

106. Plaintiff was harmed due to this reasonable reliance on Defendants' representation.

107. Plaintiff's reliance on Defendants' representation was a substantial factor in causing his harm.

Wherefore, Plaintiff JOHN SPEAR prays for judgment against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive, as set forth below.

EIGHTH CAUSE OF ACTION – CONCEALMENT (Against Defendants KNONKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive)

108. Plaintiff JOHN SPEAR incorporates by reference paragraphs 1-107 above as though fully set forth herein.

109. Philips intentionally failed to disclose certain facts regarding the serious health threats posed by the use of the Recalled Devices that were known only to Philips and that Plaintiff could not have discovered.

110. Plaintiff did not know of the concealed fact regarding the serious health threats posed by the use of the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR.

111. Philips intended to deceive Plaintiff by concealing the facts regarding the serious health threats posed by the use of the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR.

112. Had the omitted information been disclosed, Plaintiff reasonably would have stopped using the machine used by regarding the serious health threats posed by the use of the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR.

113. Plaintiff was harmed due to their use of the recalled machine.

114. Philips' concealment was a substantial factor in causing Plaintiff's harm.

Wherefore, Plaintiff JOHN SPEAR prays for judgment against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive, as set forth below.

NINTH CAUSE OF ACTION – NEGLIGENT MISREPRESENTATION (Against Defendants KNONKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive)

115. Plaintiff JOHN SPEAR incorporates by reference paragraphs 1-114 above as though fully set forth herein.

116. Philips represented to Plaintiff that use of the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR, did not pose serious health risks.

117. Philips' representation that use of the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR, did not pose serious health risks was false.

118. Philips had a duty to Plaintiff to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR.

119. Philips breached its duty to Plaintiff by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiff that did not have the qualities, characteristics, and suitability for use as advertised by Philips and by failing to promptly remove the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled Devices.

120. Philips knew or should have known that the qualities and characteristics of the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Philips. Specifically, Philips knew or should have known that:

a. The use of the Recalled Devices was accompanied by risks of adverse health effects that do not conform to the packaging and labeling;

b. The Recalled Devices were adulterated, or at risk of being adulterated, by the PE-PUR Foam; and

c. The Recalled Devices were otherwise not as warranted and represented by Philips.

121. Philips intended that Plaintiff rely on the representation that use of the Recalled Devices, including the machine used by Plaintiff JOHN SPEAR, did not pose serious health risks.

122. Plaintiff reasonably relied on Philips' representation.

123. As a direct and proximate result of Defendant's negligence, the Plaintiff has experienced serious personal injury, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment and procedures, suffered financial and economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

Wherefore, Plaintiff JOHN SPEAR prays for judgment against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, and DOES 1-100, inclusive, as set forth below.

PRAYER

WHEREFORE, with respect to each cause of action listed above, Plaintiff JOHN SPEAR prays for damages against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; PHILIPS RS NORTH AMERICA LLC; and DOES 1-100, inclusive, and each of them as follows:

1. General damages in an amount to be determined by proof at trial;
2. Special damages in an amount to be determined by proof at trial;
3. Interest as permitted by law;
4. Costs of this action;
5. Any other and further relief that the court considers proper.

DEMAND FOR JURY TRIAL

As to the matters complained of herein against Defendants KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; PHILIPS RS NORTH AMERICA LLC; and DOES 1-100, inclusive, and each of them, Plaintiff JOHN SPEAR demands a trial by jury.

Dated: August 17, 2022

Anthony Crawford

Respectfully submitted,

By: Anthony Crawford
Attorneys for Plaintiff JOHN SPEAR

EXHIBIT "A"

URGENT: Medical Device Recall

Philips Respironics
CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

To the patients who use Philips Sleep & Respiratory Care devices:

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life.[1]

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. Philips Respironics has received complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

[1] https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Immediate Actions to be taken by You, the User:

1. Talk to your health care provider to decide on a suitable treatment for your condition, which may include:
   a. Stopping use of your device
   b. **Continuing to use your affected device**, if your health care provider determines that the benefits outweigh the risks identified in the recall notification.
   c. Using another similar device that is not part of the recall or using alternative treatments for sleep apnea[2].
2. Follow the manufacturer's instructions and recommended cleaning and replacement guidelines for your CPAP machine and accessories. Ozone cleaners may exacerbate the breakdown of the foam, and there are other potential risks associated with the use of ozone and ultraviolet (UV) light products for cleaning CPAP machines and accessories.[3]
3. Report any problems with a device through the FDA's MedWatch Voluntary Reporting Form[4].
4. Register your device on the recall website www.philips.com/src-update
   a. The website provides you current information on the status of the recall and how to register with Philips to address the two (2) issues.
   b. The website provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
   c. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

Devices should be serviced only by qualified technicians. They do not include user serviceable parts. Attempts to remove the sound abatement foam may render the device permanently inoperative.

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[2] https://www.fda.gov/consumers/consumer-updates/always-tired-you-may-have-sleep-apnea

[3] https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and

[4] https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Devices damaged due to attempts by the user to remove the sound abatement foam will not be able to be remediated.

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this issue, please contact the recall support hotline or visit the website:

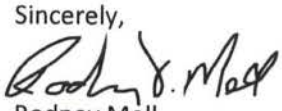
1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,



Rodney Mell
Head of Quality
Philips Respironics - Sleep & Respiratory Care

URGENT: Medical Device Recall

Philips Respironics
Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

To the patients who use Philips Sleep & Respiratory Care devices:

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during operation.[1]

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. Philips Respironics has received complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

[1] https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and

Immediate Actions to be taken by You, the User:

1. Do not stop or change ventilator use until you have talked to your health care provider.

    - Alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and in the judgment of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the potential risks identified in the recall notification.

2. Talk to your health care provider about using an inline bacterial filter, which may help to filter out particles of foam. At this time, the FDA does not have evidence of the safety and effectiveness of a filter for mitigating the foam risks, and the FDA's evaluation is ongoing.[2] It is important to note the following considerations:

    - Filters will not help to reduce exposure to certain chemicals that may be released from the PE-PUR foam.
    - Filters may affect ventilator performance because they may increase resistance of air flow through the device.
    - You should closely monitor for possible accumulation of foam debris on the filter or resistance-related problems in the breathing circuit after filter placement.
    - Consult your Instructions for Use for guidance on installation.

3. Report any problems with a device through the FDA's MedWatch Voluntary Reporting Form.[3]
4. Register your device(s) on the recall website www.philips.com/src-update
    - The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
    - The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    - Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

Devices should be serviced only by qualified technicians. They do not include user serviceable parts. Attempts to remove the sound abatement foam may render the device permanently inoperative. Devices damaged due to attempts by the user to remove the sound abatement foam will not be able to be remediated.

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[2] https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks

[3] https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this recall/issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality
Philips Respironics - Sleep & Respiratory Care